

## **REMARKS**

Claims 1-15 and 17-28 are pending in the instant specification. Applicants have amended claims 1, 2 and 26. Support for these amendments can be found, for example, page 10, lines 5-15 of the instant specification. No new matter is added.

### **Claim Rejections**

#### **35 U.S.C. § 103**

The Examiner has maintained the rejection of claims 1-15 and 18-28, on page 2 of the Office Action, under 35 U.S.C. § 103 for being obvious over Hoerstrup DE19919625 (“Hoerstrup”). First, the Examiner argued that the “broad edge” of claims 1-15 and 18-28 does not further limit the claims because the heart valves and structures of Hoerstrup could be characterized as having a broad edge. Second, the Examiner argued that even if the term “broad edge” further limited the claim, the difference between the claimed subject matter and the teachings of Hoerstrup would still be obvious because, “it has been held that changes in size, shape or proportion are an obvious design choice.”<sup>1</sup> Applicants respectfully traverse the rejection for the reasons below.

The Examiner argued that the term, “comprising a broad edge” did not further limit claims 1-15 and 18-28. Applicants respectfully disagree, however, to expedite prosecution, Applicants have added the limitation, “wherein the broad edge is a suture ring.” There is no suture ring described in Hoerstrup. No structure described in Hoerstrup could be characterized as a suture ring. Thus, Hoerstrup does not teach or suggest all of the limitations of the claims.

It is understood that the prior art is not limited to the references being applied, but also includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.<sup>2</sup> Thus, Applicants submit that claims 1-15 and 18-28 are not obvious over the teachings of Hoerstrup.

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<sup>1</sup> See page 1, paragraph 1 of the Office Action.

<sup>2</sup> MPEP § 2141

The Examiner has argued that, “it has been held that changes in size, shape or proportion are an obvious design choice,” citing In re Rose, 42 C.C.P.A. 817 (CCPA 1955);<sup>3</sup> In re Dailey, 357 F.2d 669 (CCPA 1966);<sup>4</sup> Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959)<sup>5</sup> and MPEP § 2144.04 IV. Applicants submit that this is an inaccurate interpretation of the law regarding obviousness.

In re Rose and Ex parte Rubin are not relevant to the obviousness rejection of claims 1-15 and 18-28. In re Rose deals with a difference in size of a claimed lumber package so that it could only be raised by a truck, instead of by hand as described in the prior art.<sup>6</sup> The court agreed with the Board of Patent Appeals that the size of the article under consideration is not ordinarily a matter of invention.<sup>7</sup> The facts of In re Rose do not apply in the present case as the differences between the device of Hoerstrup and that of the present claimed device are not merely a matter of size. Thus, the decision of In re Rose does not apply to the facts of the instant rejection.

Further, Ex parte Rubin deals with a difference in the order in which ingredients were added between a claimed invention and the prior art.<sup>8</sup> The Board held that a claim was obvious over the prior art, wherein the order of steps were reversed in the claims as compared to the prior art, and the criticality of the order of steps was not shown.<sup>9</sup> The order of the steps is not at issue in the instant rejection, thus, the decision in Ex parte Rubin does not apply to the facts of the instant rejection.

In re Dailey, MPEP 2144.04 IV and Gardner v. TEC Systems, Inc., 725 F.2d 1338, (Fed. Cir. 1984), cert. denied, 469 U.S. 830 (1984),<sup>10</sup> cited in MPEP § 2144.04 IV do not support the Examiner’s interpretation of the law that “it has been held that changes in size, shape or proportion are an obvious design choice.” In re Dailey involves a claimed plastic nursing container with a different shape from that shown in the prior art.<sup>11</sup> Here, the distinguishing characteristic of the claimed nursing bottle was a slit nipple with a configuration that allowed the

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<sup>3</sup> A copy is included for the Examiner’s convenience as Exhibit A.

<sup>4</sup> A copy is included for the Examiner’s convenience as Exhibit B.

<sup>5</sup> A copy is included for the Examiner’s convenience as Exhibit C.

<sup>6</sup> In re Rose, 42 C.C.P.A. 817, 822 (CCPA 1955).

<sup>7</sup> *Id.*

<sup>8</sup> Ex parte Rubin, 128 U.S.P.Q. 440, 442 (Bd. App. 1959).

<sup>9</sup> *Id.*

<sup>10</sup> A copy is included for the Examiner’s convenience as Exhibit D.

<sup>11</sup> In re Dailey, 357 F.2d 669, 672 (CCPA 1966).

nipple to self-seal, preventing air from entering the bottle.<sup>12</sup> The Circuit Court of Patent Appeals held that the configuration of the container was a mere matter of choice and was not patentable over the prior art.<sup>13</sup> The Court held this was because the prior art taught that air leaking into the bottle, and the solution to the problem, which was the nipple with the slit encompassed by the claims.<sup>14</sup> Thus, the difference in shape was not patentable because “changes in size, shape or proportion are an obvious design choice,” but because the changes were suggested in the prior art to solve problems indicated in the prior art.

In re Dailey regards claims encompassing a device useful for drying ink on high gloss paper.<sup>15</sup> The claimed device differed from a prior art device except in its dimensions, which the trial court had found as, “artificial dimensional limitations that add nothing to the claims, that are of no constructive significance, and are essentially meaningless.”<sup>16</sup> The Federal Circuit agreed.<sup>17</sup> The claimed device performed no differently than the prior art device despite the dimensional differences.<sup>18</sup> The Federal Circuit framed the issue of this case as to whether the structural differences of the claimed device and the prior art resulted in differences in performance.<sup>19</sup> The patent holder in In re Dailey failed to show that the structural differences of their device resulted in differences in performance, so the Federal Circuit held that their claims were unpatentable over the prior art.<sup>20</sup>

Likewise, MPEP § shows summaries of In re Rose, In re Dailey, Ex parte Rubin and Gardner v. TEC Systems, Inc. that support the arguments Applicants have made above. The MPEP does not support a rule that states that “it has been held that changes in size, shape or proportion are an obvious design choice.” The MPEP and the relevant case law states that changes in size, shape or proportion are only obvious if they are taught or suggested in the prior art or if the changes do not result in a difference in performance over the prior art.

The suture ring limitation of claims 1-15 and 18-28 is not taught or suggested by Hoerstrup and the presence of the suture ring results in a change in performance in the device of

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<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 1339 (Fed. Cir. 1984).

<sup>16</sup> *Id.* at 1344.

<sup>17</sup> *Id.* at 1345.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* at 1346.

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claims 1-15 and 18-28 over the device described in Hoerstrup. Thus, claims 1-15 and 18-28 are not obvious over the teachings of Hoerstrup.

Hoerstrup does not teach any suture ring, let alone the suture ring encompassed by claims 1-15 and 18-28. Thus, Hoerstrup does not teach or suggest the limitations of claims 1-15 and 18-28 and the Examiner has not provided an explanation as to why the differences would be obvious to one of ordinary skill in the art.

Further, the differences between the device described in claims 1-15 and 18-28 result in a change in performance of the claimed device over the device described in Hoerstrup. Using this suture ring with the device of the invention allows easier implantation of the device by surgeons, while the autologous tissue engineering component of the device is not compromised. Thus, the presence of a suture ring composed of a biodegradable support provides greater performance for the device of claims 1-15 and 18-28 over the prior art device. Thus, the changes in shape to the device are not an obvious design choice and render claims 1-15 and 18-28 non-obvious over the teachings of Hoerstrup based on the case law and MPEP section cited by the Examiner.

Applicants respectfully request that this rejection be withdrawn.

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### **CONCLUSION**

A favorable action on the merits is respectfully requested. If further discussion of this case is deemed helpful, the Examiner is encouraged to contact the undersigned at the telephone number provided below, and is assured of full cooperation in progressing the instant claims to allowance.

Respectfully submitted,

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